DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2015

Contract Medical International GmbH
Jan Kloboucnik
Director, Regulatory and Quality Affairs
Lauensteiner Str, 37
Dresden, 01277 DE

Re: K142357
Trade/Device Name: DuraSheath Introducer Sheath System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: May 21, 2015
Received: May 26, 2015

Dear Jan Kloboucnik,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142357

Device Name
DuraSheath Introducer Sheath System

Indications for Use *(Describe)*
The DuraSheath Introducer Sheath System is indicated to be used for introduction of interventional and diagnostic devices into the human vasculature, including but not limited to femoral access via a contralateral approach to access the popliteal and infrapopliteal arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K142357 - 510(k) Summary

1.1 Submitter

Submitter:	Contract Medical International GmbH Lauensteiner Straße 37 01277 Dresden Germany
Contact Person:	Jan Kloboucnik, Director, RA/QA
Phone:	+420 494 949 564
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Email:	jkloboucnik@contract-medical.com
Date Prepared:	24 June 2015

1.2 Device

Device Trade Name:	DuraSheath Introducer Sheath System
Device Common Name:	Introducer Sheath
Classification Name:	Introducer, Catheter; and Dilator, Vessel, For Percutaneous Catheterization
Regulatory Class:	II
Product Code:	DYB; and DRE

1.3 Predicate Device

Primary Predicate Device:	Pinnacle Destination Guiding Sheaths (K091329)
Second Predicate Device:	Fortress Introducer Sheath System (K100799)

1.4 Device Description

The DuraSheath Introducer Sheath System is a sterile, disposable device consisting of (a) a coil reinforced shaft with an atraumatic tip at the distal end; (b) a hemostasis valve with a side port and color coded 3-way stopcock; and (c) a tapered tip dilator with snap-fit hub at the proximal end. The distal end of the sheath contains a radiopaque marker. Lubricous coating is applied to the distal end of the sheath. The system is packaged inside a sealed Tyvek pouch.

The DuraSheath Introducer Sheath System is a prescription medical device that is used only in healthcare facilities or hospitals. The device is placed in patients for up to 24 hours.

1.5 Indications for Use

The DuraSheath Introducer Sheath System is indicated to be used for introduction of interventional and diagnostic devices into the human vasculature, including but not limited to femoral access via a contralateral approach to access the popliteal and infrapopliteal arteries.

The Indications for Use statement for the DuraSheath Introducer Sheath System is not identical to that of the two predicate devices; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate devices. The DuraSheath Introducer Sheath System and the two predicate devices each have the same intended use, namely to support the introduction of interventional and diagnostic devices.

1.6 Comparison of Technological Characteristics with the Predicate Device

The DuraSheath Introducer Sheath System is a manually operated, sterile, single patient use sheath system made predominantly of thermoplastic polymers. The sheath is reinforced with a stainless steel coil in order to provide kink resistance when passed through tortuous paths. With regard to the design, device features, method of sterilization, and mode of operation, the DuraSheath Introducer Sheath System does not differ from the predicate devices. Materials used for manufacture of the DuraSheath Introducer Sheath System are the same or very similar to those contained in the predicate devices. Technological characteristics of the subject device differ from those of the predicates only with respect to materials for selected components and the choice of lubricious coating on the sheath. Both the polyurethane used for the outer layer and the hydrophobic coating applied to the distal end of the sheath of the DuraSheath Introducer Sheath System are commonly used in medical devices, including introducer sheaths and catheters. Differences in technological characteristics between the subject device and the predicates do not raise and concerns of safety and effectiveness, as demonstrated by the performance data collected.

1.7 Performance Data

Nonclinical and clinical performance data demonstrate that the DuraSheath Introducer Sheath System is safe and effective and performs substantially equivalent to the predicates. The following performance data from non-clinical tests are being provided in support of the substantial equivalence determination:

- Mechanical testing, including tests required under relevant international standards, coating adhesion and particulate testing, and transportation integrity testing, performed to verify and validate the design and to demonstrate process capability.
- Full range of Biocompatibility testing to demonstrate biocompatibility.
- Sterilization Validation Adoption to confirm sterility of the device upon exposure to the selected sterilization cycle.
- Accelerated age testing to confirm product performance and end of shelf life.

1.8 Conclusions

Results demonstrate that the DuraSheath Introducer Sheath System performs comparably with predicates and other legally marketed devices. The DuraSheath Introducer Sheath System is substantially equivalent to the two predicates devices in terms of intended use, design and materials, technological characteristics, and principle of operation. Any differences between the subject device and the predicates do not raise any issues of safety or effectiveness.